UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,458	07/05/2001	David Frederick Horrobin	P66731US0	8131

7590 04/07/2003

JACOBSON HOLMAN
PROFESSIONAL LIMITED LIABILITY COMPANY
400 SEVENTH STREET, N.W.
WASHINGTON, DC 20004

EXAMINER
CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
1615	11

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/898,458	Applicant(s) HORROBIN, DAVID FREDERICK	
	Examin r Lakshmi S Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *10-21 and 31-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 22-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4, 5, 8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of the following is acknowledged:

1. Declaration and fee, dated 10-17-01,

2. IDS, dated 10-1-01,

3. Supplemental IDS and priority papers, dated 11-2-01,

4. Third IDS, dated 11-8-01, and

5. Request for extension of time and response dated 1-13-03.

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-9 and 22-30) in Paper No. 10 is acknowledged.

Examiner inadvertently stated claims 1-9 and 22-30 under group II, in paper # 7. However, as applicants correctly pointed out Group I constitute claims 1-9 and 22-30 and Group II constitutes claims 10-17 and 31-38.

Claim Rejections - 35 USC § 112

2. Claims 8 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claims recite the phrase "consists essentially wholly of", which is indefinite because it is unclear from the term if applicants intend to claim a composition consisting of vitamin and EFA or a composition consisting essentially of vitamin K and EFA. Besides,

applicants have not defined what constitutes "essentially wholly of". A clarification and appropriate correction is requested. For examination purpose, examiner considers the expression as "consisting essentially of".

3. Claims 22-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The invention provides a nutritional or pharmaceutical formulation containing a combination of a source of vitamin K and a source of at least one essential fatty acid (EFA), wherein the concentration of vitamin K is not less than 1000 micrograms/100 grams. The invention describes a method of treating and preventing a variety of diseases using the above composition.

Vitamin K, is widely distributed in foods, is known to be important co-factor for the enzyme gamma-glutamylcarboxylase, in the synthesis of blood clotting proteins (Gla proteins). The relation between Vitamin K diseases such as osteoporosis and hypothrombinemia has been established and several studies suggest vitamin K supplementation for bone fractures and osteoporosis. Further, essential fatty acids, found in fish oils or vegetable oils, are known for their antioxidant activity and for their efficacy in reducing the risk of infections.

Instant claims recite a method of treating or preventing a variety of diseases using the composition of vitamin K and EFA, in which the concentration of Vitamin K not less than 1000 micrograms/100 grams. Instant claims are broad in that they recite preventing the diseases and also recite the diseases broadly. For instance, claim 30 recites premenstrual or menstrual disorders of any kind; metabolic disorders; mental, psychiatric, psychological disorders; any form of inflammatory disorders etc. Thus, the claim is directed to diseases or disorders that are yet to be discovered as caused due to the deficiency of vitamin K and EFA.

Instant specification describes the source of vitamin K and essential fatty acids and their daily-recommended dosages. Further, the specification describes the associated of Vitamin K with bone disorders and the nutritional requirement of EFAs, in terms of normal structure and function of cells and cell membranes. However, the specification does not teach or provide any written description of all the conditions or diseases or disorders that arise due to a deficiency of Vitamin K, other than osteoporosis and bone fractures. Nor the specification provides any rationale to believe that treating osteoporosis by vitamin K and EFA supplementation also prevents other claimed diseases and disorders. Specification does not teach or describe the role of vitamin K or EFA in the claimed diseases, for instance, inflammatory, respiratory or

gastrointestinal diseases etc. The only examples provided in the specification are directed to treating atopic dermatitis and premenstrual syndrome by providing a nutritional supplement containing the claimed composition. However, instant specification does not provide any examples of preventing any of the claimed diseases. Specification also does not provide any guidance as to how to identify patients that would eventually develop any of the claimed diseases or disorders. Therefore, it is examiner's position, that one of an ordinary skill in the art would have to perform undue experimentation to recognize any or all the diseases that are caused to the deficiency of vitamin K and EFA, in order to be to be able to treat or prevent such disorders, in which no correlation between the disease or disorder and the levels of vitamin K and EFA has been established.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 8, 9, 22, 25, 26, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,719,134 to Schmidl et al (Schmidl).

Independent claim 1 is a nutritional or pharmaceutical formulation containing a combination of a source of vitamin K and a source of at least one essential fatty acid (EFA), wherein the concentration of vitamin K is not less than 1000 micrograms/100 grams. Independent claim 22 recites a method of treating or preventing a variety of diseases by administering the composition of claim 1. Claims 4 and 25 require vitamin K1, claims 5 and 26

recite specific EFAs, claims 8 and 29 recite the composition consists essentially of vitamin K and EFA as the active ingredient; and claims 9 and 30 recite that the composition contain other vitamins and/or minerals.

Schmidl discloses nutritional compositions for adolescents comprising carbohydrates, vitamins, lipids etc., for treating disease conditions such as inflammatory bowel syndrome, AIDS, GI fistula etc. Examiner notes that instant claim recites not less than 1000micrograms (1 mg) per 100 grams, which is 0.001%. Schmidl discloses vitamin K1in the range of 0.0025% to 0.0031 % by weight of the composition (col. 4, last line in the table), which is above the claimed range. Accordingly, the % of vitamin K1 disclosed by Schmidl reads on the instant claimed amount. Schmidl also discloses soybean oil in their composition, as a source of essential fatty acids (col. 2, lines 40-64 and table in col. 4). In particular, Schmidl discloses linolenic and linoleic acids as (col. 2, lines 60-64), which read on claims 5 and 26. With respect to claims 8 and 29, please refer to the 35 USC 112, rejection as indefinite. Schmidl teaches that the nutritional composition is well balanced with the required vitamins, minerals, lipids, carbohydrates etc. Accordingly, it is implicit that essential fatty acids and vitamin k1 are active ingredients in the composition of Schmidl. Schmidl teaches the composition for treating diseases such as cystic fibrosis, lactose intolerance etc., and thus meet the requirement of claim 22.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 3, 6, 7, 23, 24, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,719,134 to Schmidl et al (Schmidl) in view of US 4,977,187 ('187).

Schmidl discussed above fails to teach the specific EFA of instant claims and also lacks the specific daily-recommended doses of the instant claims.

'187 teaches EFAs selected n-6 and n-3 series such as arachidonic acid, gamma-linoleic acid, adrenic acid etc (col. 2), such as those claimed in the instant invention, in medicament compositions for treating schizophrenia. '187 teaches that the EFAs are active anti-oxidants and inhibit free radical generation, and have a role in reversing the damage caused by free radicals in a number of diseases including cystic fibrosis, schizophrenia etc (col. 3).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the EFAs of '187 in the nutritional composition of Schmidl because '187 teaches that specific EFAs of n-6 and n-3 series such as arachidonic acid, adrenic acid, eicosapentaenoic acid etc., possess high anti-free radical activity and are therefore very effective in treating diseases such as inflammation, irritable bowel syndrome, cystic fibrosis, etc., which are also being treated by Schmidl. Accordingly, one of an ordinary skill in the art would expect the specific EFAs of '187 to enhance the value of the nutritional composition of Schmidl in terms of its efficacy in treating the above diseases. With respect to the claimed daily dosages, absent criticality, optimizing the amounts of the individual components for achieving the art recognized effect, in the nutritional composition of Schmidl, would have been within the scope of a skilled artisan.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Lakshmi S Channavajjala
Examiner
Art Unit 1615
April 3, 2003